# Alkylbenzene Sulfonates

# Interim Registration Review Decision
# Case Number 4006

## May 2020

Approved by: _____

Anita Pease
Director
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# I. INTRODUCTION

This document is the Environmental Protection Agency's (the EPA or the agency) Interim Registration Review Decision (ID) for alkylbenzene sulfonates (ABS) (PC Codes 098002 and 079010; case 4006) and is being issued pursuant to 40 CFR §§ 155.56 and 155.58. A registration review decision is the agency's determination whether a pesticide continues to meet, or does not meet, the standard for registration in the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). The agency may issue, when it determines it to be appropriate, an interim registration review decision before completing a registration review. Among other things, the interim registration review decision may require new risk mitigation measures, impose interim risk mitigation measures, identify data or information required to complete the review, and include schedules for submitting the required data, conducting the new risk assessment and completing the registration review. Additional information on alkylbenzene sulfonates can be found in the EPA's public docket (EPA-HQ-OPP-2013-0097) at www.regulations.gov.

FIFRA, as amended by the Food Quality Protection Act (FQPA) of 1996, mandates the continuous review of existing pesticides. All pesticides distributed or sold in the United States must be registered by the EPA based on scientific data showing that they will not cause unreasonable risks to human health or to the environment when used as directed on product labeling. The registration review program is intended to make sure that, as the ability to assess and reduce risk evolves and as policies and practices change, all registered pesticides continue to meet the statutory standard of no unreasonable adverse effects. Changes in science, public policy, and pesticide use practices will occur over time. Through the registration review program, the agency periodically re-evaluates pesticides to make sure that as these changes occur, products in the marketplace can continue to be used safely. Information on this program is provided at http://www.epa.gov/pesticide-reevaluation. In 2006, the agency implemented the registration review program pursuant to FIFRA § 3(g) and will review each registered pesticide every 15 years to determine whether it continues to meet the FIFRA standard for registration.

EPA is issuing an interim decision for ABS so that it can move forward with aspects of the registration review that are complete. The agency has evaluated risks to listed species and is making a "no effect" finding for listed species and designated critical habitat and has therefore concluded that consultation with the Fish and Wildlife Service and the National Marine Fisheries Service under Endangered Species Act (ESA) section 7(a)(2) is not required. The agency will complete endocrine screening for ABS, pursuant to the Federal Food, Drug, and Cosmetic Act (FFDCA) § 408(p), before completing registration review. See the *Proposed Interim Registration Review Decision for ABS* Appendices A and B, respectively, for additional information about the endangered species assessment and the endocrine screening for the registration review of ABS[1].

This document is organized in five sections: the *Introduction*, which includes this summary and a summary of public comments and the EPA's responses; *Use and Usage*, which describes how and why ABS is used and summarizes data on its use; *Scientific Assessments*, which summarizes the EPA's risk and benefits assessments, updates or revisions to previous risk assessments, and provides broader context with a discussion of risk characterization; the *Interim Registration*

[1] The *Proposed Interim Registration Review Decision for ABS* document is located at www.regulations.gov in docket EPA-HQ-OPP-2013-0097.

*Review Decision*, which describes the regulatory rationale for the EPA's interim registration review decision; and, lastly, the *Next Steps and Timeline* for completion of this registration review.

## A. Summary of Alkylbenzene Sulfonates Registration Review

Pursuant to 40 CFR § 155.50, EPA formally initiated registration review for ABS with the opening of the registration review docket (case 4006) in 2013. The following summary highlights the docket opening and other significant milestones that have occurred thus far during the registration review of alkylbenzene sulfonates. Additional information can be found in EPA's public docket, EPA-HQ-OPP-2013-0097, accessed at www.regulations.gov.

- March 2013- The *Alkylbenzene Sulfonates Preliminary Work Plan* (PWP*)*, was posted to the docket for a 60-day public comment period.

- September 2013- The *Alkylbenzene Sulfonates Final Work Plan* (FWP) was published. The agency received one comment on the PWP. The comment received did not affect the data needs of the work plan and timeline described in the PWP.

- December 2018- The *Alkylbenzene Sulfonates Amended Final Work Plan* was published after the agency identified additional residue chemistry and toxicology data requirements necessary to support a dietary risk assessment of ABS.

- December 2018 [GDCI-098002-1766 and GDCI-079010-1757]- A Generic Data Call-In (GDCI) for alkylbenzene sulfonates was issued for data needed to conduct the registration review risk assessments. These were published on the docket in March 2019.

- September 2019 - The agency announced the availability of *Alkylbenzene Sulfonates (ABS) Registration Review Draft Risk Assessment* (DRA) for a 60-day public comment period. Two comments were received during this time from two sources; Ecolab Inc. and a general public source. The comments did not change the risk assessments or registration review timeline for alkylbenzene sulfonates.

- September 2019 - Supported by the DRA, a tolerance exemption for ABS was established and posted to docket number EPA-HQ-OPP-2018-0070.

- December 2019- Regulatory waiver published to waive outstanding data from the 2018 GDCI except GLN 875.1700 (Product Use Information).

- February 2020 - The agency announced the availability of *Alkylbenzene Sulfonates Registration Review Proposed Interim Decision* (PID) for a 60-day public comment period. One comment was received from the U.S. Department of Agriculture (USDA), and this comment did not change the regulatory conclusions of the PID.

- May 2020 – The agency has completed the *Alkylbenzene Sulfonates Registration Review Interim Decision* and will announce its availability in the Federal Register and place it in docket EPA-HQ-OPP-2013-0097.

### B. Summary of Public Comments on the Proposed Interim Decision and Agency Responses

During the 60-day public comment period for the *Alkylbenzene Sulfonates (ABS) Registration Review Proposed Interim Decision*, which opened on February 4, 2020 and closed on April 6, 2020, the agency received one comment from the USDA expressing support for the continued registration of ABS and for the "no effects" finding under the ESA. The EPA thanks USDA for their comment.

## II. USE AND USAGE

The two active ingredients of the ABS case are sodium dodecylbenzene sulfonate (SDBS; PC code 079010) and dodecylbenzene sulfonic acid (DDBSA; PC code 098002). DDBSA has five registered products and SDBS has three registered products. Products containing ABS are registered for antimicrobial uses in fruit and vegetable washes and in cleaners and sanitizers in residential and commercial areas, including food and non-food contact areas. All products in all use sites are intended to reduce pathogens and control spoilage and decay caused by microorganisms, and to control bacteria. The first product containing sodium dodecylbenzene sulfonate as an active ingredient was registered in the United States in 1968. The first product containing dodecylbenzene sulfonic acid was registered in 1969. The agency completed a Reregistration Eligibility Decision (RED) for ABS in 2006. Reregistration for products containing ABS is on-going.

ABS is also registered as an inert ingredient (solvents, surfactants, dispersants, detergents, or wetting agents) in approximately 350 registered end-use products. Products that contain alkylbenzene sulfonates as an inert are designated for use in agricultural settings, food handling premises, medical premises, commercial/ institutional/ industrial settings, and residential settings. Specified use sites for the pesticide products containing ABS as an inert include the following: indoor hard nonporous surfaces (*e.g.*, floors, walls, *etc*.), carpets, food contact surfaces (glasses, dishes, silverware, countertops, *etc*.), agricultural tools and crops, lawns and turfs, fruits and vegetables (post-harvest), wood preservatives, materials preservatives, and metalworking fluids.

A petition was submitted requesting the establishment of an exemption from the requirement of a tolerance for C10-C16 branched and linear alkylbenzene sulfonates (ABS), when used as an active ingredient not to exceed 700 ppm in antimicrobial formulations applied to surfaces, as described in 40 CFR 180.940(a). This petition was granted and made into a final rule on September 9, 2019. It can be found on www.regulations.gov in docket EPA-HQ-OPP-2018-0070. Section III.A.3. provides more detail about this tolerance exemption.

## III. SCIENTIFIC ASSESSMENTS

## A. Human Health Risks

A summary of the agency's human health risk assessment is presented below. The agency used the most current science policies and risk assessment methodologies to prepare a risk assessment in support of the registration review of alkylbenzene sulfonates. For detailed discussions of all aspects of the human health assessment, see the *Alkylbenzene Sulfonates Registration Review Draft Risk Assessment*[2].

### 1. Risk Summary and Characterization

A summary of the agency's human health risk assessment was presented in the PID. The EPA concluded there are no dietary, residential, occupational, aggregate, or cumulative risks of concern for ABS.

Since the PID, there have been no changes to the agency's previous human health risk conclusions. For additional details, see the *Registration Review Draft Risk Assessment for ABS* published September 30, 2019 and the ABS *Proposed Interim Registration Review Decision* published February 4, 2020. Both of these documents can be found in the EPA's public docket for ABS (EPA-HQ-OPP-2013-0097) at http://www.regulations.gov.

### 2. Human Incidents

The OPP Incident Data System (IDS) currently has no human incidents to report as of April 8, 2020. The agency will continue to monitor the incident information. Additional analyses will be conducted if ongoing human incident monitoring indicates a concern.

### 3. Tolerances

As of December 2019, the EPA has established various exemptions from the requirement of a tolerance for ABS (including SDBS and DDBSA) under the Federal Food, Drug, and Cosmetic Act (FFDCA) Section 408. The registrant submitted a petition on September 28, 2017 to establish an exemption from the requirement of a tolerance for branched and linear alkylbenzene sulfonates (ABS) of chain lengths C10-C16 used as active ingredients at 700 ppm in antimicrobial pesticide formations as described in 40 CFR §180.940(a). 40 CFR §180.940 lists tolerance exemptions for active and inert ingredients for use in antimicrobial formulations (food-contact surface sanitizing solutions). Paragraph (a) clarifies that the listed "chemical substances when used as ingredients in an antimicrobial pesticide formulation may be applied to: food-contact surfaces in public eating places, dairy processing equipment, and food processing equipment and utensils." This petition was made into a final rule on September 9, 2019 and can be found on www.regulations.gov in docket EPA-HQ-OPP-2018-0070.

Due to the similarity of production methods, product mixtures, and commercial use sites, as well as the similar or identical physical, chemical, and toxicological properties of ABS compounds, one dietary risk assessment covering both linear and branched ABS compounds of chain lengths

[2] *Registration Review Draft Risk Assessment for Alkylbenzene Sulfonates"* (2019) available at https://www.regulations.gov/document?D=EPA-HQ-OPP-2013-0097-0008

C10-C16 was performed. This is consistent with the ABS RED and other risk assessments. Table 1 provides a summary of the established tolerance for commercial, not residential, products containing ABS.

**Table 1: Summary of Tolerance Exemption located in docket EPA-HQ-OPP-2018-0070**

| **Alkylbenzene Sulfonates 40 CFR § 180.940: Summary of Tolerance Exemption** | | | |
|---|---|---|---|
| Use Site | Previous Tolerance (ppm) | Newly Established Tolerance (ppm) | Comments |
| Dairy-processing equipment, and food-processing equipment and utensils | 5.5 | 700 | This tolerance is for residues of C10-C16 branched and linear ABS, including active ingredients in the alkylbenzene sulfonates case (4006), benezenesulfonic acid, dodecyl and benzenesulfonic acid, dodecyl-, sodium salt, when used as an active or inert ingredient in antimicrobial pesticide formulations |
| Food-processing equipment and utensils | 400 | 700 | |
| Food contact surfaces in public eating places | N/A | 700 | |

### 4. Human Health Data Needs

Since the PID, there have been no changes to the agency's human health data needs, and the data requirement GLN 875.1700 is the sole outstanding remaining study registrants are required to respond in full to the agency.

## B. Ecological Risks

A summary of the agency's ecological risk assessment is presented below. The agency used the most current science policies and risk assessment methodologies to prepare a risk assessment in support of the registration review of alkylbenzene sulfonates. For additional details on the ecological assessment for ABS see the *Alkylbenzene Sulfonates Registration Review Draft Risk Assessment* which is available on www.regulations.gov in the public docket EPA-HQ-OPP-2013-0097.

### 1. Risk Summary and Characterization

ABS exhibits low to moderate toxicity to nontarget organisms. The only expected environmental exposure route is from residues going down-the-drain (DtD) after use. These chemicals are extremely biodegradable and show strong sorption to sludge in wastewater treatment. Therefore, minimal environmental exposure to both terrestrial (including pollinators) and aquatic organisms is expected from the registered uses of ABS. Based on these facts, no risk to terrestrial (including

pollinators) and aquatic nontarget organisms is expected for ABS. In addition, the agency has made a "no effect" determination for the registered uses of ABS under the ESA.

#### 2. Ecological Incidents

A search of the agency's Incident Data System (IDS) on April 8, 2020 did not identify any ecological incidents from the use of products containing ABS. The agency will continue to monitor ecological incident information as it is reported to the agency. Detailed analyses of these incidents are conducted if reported information indicates concerns for risk to non-target organisms.

#### 3. Ecological and Environmental Fate Data Needs

No major uncertainties were identified and there are no ecological or environmental fate data gaps for ABS.

## IV. INTERIM REGISTRATION REVIEW DECISION

### A. Risk Mitigation and Regulatory Rationale

In this *Alkylbenzene Sulfonates Interim Registration Review Decision,* the agency determined that there are no human health or ecological risks of concern for the uses of alkylbenzene sulfonates. Therefore, risk mitigation measures are not needed at this time. One comment in support of the use of ABS and the ESA "no effects" finding was received during the public comment period for the PID, and the agency has not made any changes to what was proposed in the PID.

### B. Tolerance Actions

A tolerance exemption petition document was posted to docket EPA-HQ-OPP-2018-0070 in November 2018. This petition requested the establishment of an exemption from the requirement of a tolerance for C10-C16 branched and linear ABS, when used as an active ingredient not to exceed 700 ppm in antimicrobial formulations applied to surfaces described in 40 CFR 180.940(a). This petition was granted and a tolerance exemption was established by final rule on September 9, 2019 and can be found on www.regulations.gov in docket EPA-HQ-OPP-2018-0070. Refer to Section III.A.3 for details.

### C. Data Requirements

The agency does not require additional data for ABS at this time.

## V. NEXT STEPS AND TIMELINE

### A. Interim Registration Review Decision

In accordance with 40 CFR sections §§ 155.56 and 155.58, the agency is issuing the *Alkylbenzene Sulfonates Interim Registration Review* Decision. A Federal Register Notice will announce the availability of this Interim Decision for alkylbenzene sulfonates. The agency has made a "no effect" determination under ESA for ABS, and the agency's final registration review decision for ABS will be dependent upon the result of the EDSP FFDCA section § 408(p) determination. See the *Proposed Interim Registration Review Decision for ABS* Appendices A and B, respectively, for additional information about the endangered species assessment and the endocrine screening for the registration review of ABS.

### B. Implementation of Mitigation Measures

This interim decision does not include any risk mitigation measures for ABS.